UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,634	10/27/2003	Jun Tan	4303-032029	2636

28289 7590 04/24/2006

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,634	TAN ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-92 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-92 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-92 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a research model for screening compounds suspecting of modulating the CD40L/CD40R signaling pathway by contacting a first cell with CD40 ligand and measuring the activity of a marker, contacting a second cell with a compound and CD40 ligand and measuring the activity of the marker, and comparing the level of the marker in the first cell with the level of the marker in the second cell, classified in class 435, subclass 375.

II. Claims 21-39, drawn to drawn to a research model for screening compounds suspecting of modulating the CD40/CD40R signaling pathway by contacting CNS or peripheral cells expressing CD40R with CD40L and a compound, and measuring a marker, contacting CNS or peripheral cells with a stimulator or inhibitor of the CD40L/CD4040R signaling pathway, and comparing the markers, classified in class 435, subclass 375.

III. Claims 40-53, drawn to a method of identifying compounds that ameliorate symptoms associated with a disease by administering, to a subject, a compound that modulates the CD40L/CD4040R signaling pathway, and observing the amelioration of the synptoms, classified in class 514, subclass 44.

IV. Claims 54-70, drawn to a method of treating a disease by administering to a subject a therapeutically effective amount of a carrier and an agent that interferes with the CD40L/CD4040R signaling pathway or the phosphorylation of tau protein, classified in class 514, subclass 44.

V. Claims 71-92, drawn to a method of causing a desired biological effect in a subject afflicted with a disease by administering to a subject a therapeutically effective amount of a carrier and an agent that interferes with the CD40L/CD4040R signaling pathway, classified in class 514, subclass 44.

3. Should invention of Group I be elected for prosecution, species election is required as follows

The presently pending claims 1-20 are generic to a plurality of disclosed patentably distinct species comprising:

A. Animal, human, or system (claim 1);

- Should animal be elected for prosecution, a single animal must be elected from those recited in claim 19.
- Should the transgenic animal of claim 19 be elected for prosecution, a single transgenic animal must be elected from those recited in claim 20.

B. Distinct species of cells (claim 2);

C. Distinct species of markers (claim 3 and 5-7);

- Should combination be elected for prosecution, Applicant is required to elect a specific combination
- Should cytokine be elected for prosecution, a single species must be elected from the species recited in claim 4. Should combination of cytokines be elected for prosecution, Applicant is required to elect one specific combination.

D. Distinct species of compounds (claim 8);

Should interfering RNA be elected for prosecution, a further species election is required as follows:
- CD40L, CD40R, or beta-amyloid (claim 9);
- 70% (claim 10) or 95% (claim 11);
- 15-25 nucleotides (claim 12), 25 nucleotides (claim 13), 50 nucleotides (claim 14) or one nucleotide less (claim 15).

Applicant is required under 35 U.S.C. 121 to elect one species from each of the above groups of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

E. Distinct species of diseases (claim 16);

- Should amyloidogenic disease be elected for prosecution, a single species must be elected from the species recited in claim (17).
- Should taupathy be elected for prosecution, a single species must

Applicant is required under 35 U.S.C. 121 to elect one species from each group A to E, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Should invention of Group II be elected for prosecution, species election is required as follows

The presently pending claims 21-39 are generic to a plurality of disclosed patentably distinct species comprising:

A. Animal, human or system (claim 1);

- Should animal be elected for prosecution, a single animal must be elected from those recited in claim 38.
- Should the transgenic animal of claim 38 be elected for prosecution, a single transgenic animal must be elected from those recited in claim 39.

B. CNS or peripheral cells (claim 21);

C. Stimulator or inhibitor (claim 21);

D. Distinct species of markers (claim 21 and 24-26);

- Should combination be elected for ptrosecution, Applicant is required to elect a specific combination.
- Should cytokine be elected for prosecution, a single cytokine must be elected from the species recited in claim 23. Should combination be elected for prosecution, Applicant is required to elect one specific combination of cytokines.

E. Distinct species of compounds (claim 27);

Should interfering RNA be elected for prosecution, a furhter species election is required as follows:

- CD40L, CD40R, or beta-amyloid (claim 28);
- 70% (claim 29) or 95% (claim 30);
- 15-25 nucleotides (claim 31), 25 nucleotides (claim 32), 50 nucleotides (claim 33) or one nucleotide less (claim 34).

Applicant is required under 35 U.S.C. 121 to elect one species from each of the above groups of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

F. Distinct species of diseases (claim 35);

- Should amyloidogenic disease be elected for prosecution, a single species must be elected from the species recited in claim (36).
- Should taupathy be elected for prosecution, a single species must be elected from the species recited in claim (37).

Applicant is required under 35 U.S.C. 121 to elect one species from each group A to F, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Should invention of Group III be elected for prosecution, species election is required as follows

The presently pending claims 40-53 are generic to a plurality of disclosed patentably distinct species comprising:

A. Distinct species of diseases (claim 40);

- Should amyloidogenic disease be elected for prosecution, a single species must be elected from the species recited in claim (50).
- Should taupathy be elected for prosecution, a single species must be elected from the species recited in claim (51).

B. Animal, human, or system (claim 40);

- Should animal be elected for prosecution, a single animal must be elected from those recited in claim 52.
- Should the transgenic animal of claim 52 be elected for prosecution, a single transgenic animal must be elected from those recited in claim 53.

C. Distinct species of compounds (claim 41);

Should interfering RNA be elected for prosecution, a further species election is required as follows:

- CD40L, CD40R, or beta-amyloid (claim 42);
- 70% (claim 43) or 95% (claim 44);
- 15-25 nucleotides (claim 45), 25 nucleotides (claim 46), 50 nucleotides (claim 47) or one nucleotide less (claim 48).

Applicant is required under 35 U.S.C. 121 to elect one species from each of the above groups of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

D. Distinct species of symptoms (claim 49).

Should combination be elected for prosecution, Applicant is required to elect a specific combination.

Applicant is required under 35 U.S.C. 121 to elect one species from each group A to D, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Should invention of Group IV be elected for prosecution, species election is required as follows

The presently pending claims 54-69 are generic to a plurality of disclosed patentably distinct species comprising:

A. Distinct species of diseases (claim 54);

- Should amyloidogenic disease be elected for prosecution, a single species must be elected from the species recited in claim (63).
- Should taupathy be elected for prosecution, a single species must be elected from the species recited in claim (64).

B. CD40L/CD40R signaling pathway or phosphorylation of tau (claim 54);

C. Distinct species of compounds (claim 55);

Should interfering RNA be elected for prosecution, a furhter species election is required as follows:

- CD40L, CD40R, or beta-amyloid (claim 56);
- 70% (claim 57) or 95% (claim 58);
- 15-25 nucleotides (claim 59), 25 nucleotides (claim 60), 50 nucleotides (claim 61) or one nucleotide less (claim 62).

Applicant is required under 35 U.S.C. 121 to elect one species from each of the above groups of species, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

D. Parenteral, oral, or intraperitoneal (claim 66);

- Should parenteral be elected for prosecution, a single species must be elected from the species recited in claim 67;
- Should oral be elected for prosecution, a single species must be elected from the species recited in claim 68;
- Should nasal be elected for prosecution, a single species must be elected from the species recited in claim 69.

Applicant is required under 35 U.S.C. 121 to elect one species from each group A to D, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Should invention of Group V be elected for prosecution, species election is required as follows:

The presently pending claims 71-83, 85, and 88-92 are generic to a plurality of disclosed patentably distinct species comprising:

A. Distinct species of diseases (claim 71);

- Should amyloidogenic disease be elected for prosecution, a single species must be elected from the species recited in claim (73).
- Should taupathy be elected for prosecution, a single species must be elected from the species recited in claim (74).

B. Distinct species of biological effect (claim 72);

Should combination be elected for prosecution, Applicant is required to elect a specific combination.

C. Distinct species of compounds (claims 75, 83, and 85);

- Should combination be elected for prosecution, Applicant is required to elect a specific combination.
- Should interfering RNA be elected for prosecution, a furhter species election is required as follows:
  - CD40L, CD40R, or beta-amyloid (claim 76);
  - 70% (claim 77) or 95% (claim 78);
  - 15-25 nucleotides (claim 79), 25 nucleotides (claim 80), 50 nucleotides (claim 81) or one nucleotide less (claim 82).

D. Parenteral, oral, or intraperitoneal (claim 88);

- Should parenteral be elected for prosecution, a single species must be elected from the species recited in claim 89;
- Should oral be elected for prosecution, a single species must be elected from the species recited in claim 90;
- Should nasal be elected for prosecution, a single species must be elected from the species recited in claim 91.

Applicant is required under 35 U.S.C. 121 to elect one species from each group A to D, even though this requirement is traversed. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. The inventions of Groups I and II are patentably distinct because they are drawn to methods that have distinct steps and require different compositions for practice. For example, the method of Group I requires comparing the activity of a marker in a first cell contacted with a CD40 ligand with the activity of the same marker in a second cell contacted with a compound and CD40 ligand, whereas the method of Group II requires comparing the activity of a marker in a cell contacted with CD40 ligand and a compound with the activity of the same marker in a cell contacted with a stimulator or inhibitor of the CD40L/CD40R signaling pathway.

The inventions of Groups I/II and III-V are patentably distinct because they are drawn to methods that have distinct steps and require different compositions for practice. The methods of Groups I and II are drawn to *in vitro* screening for agents that can modulate the CD40L/CD40R, while the methods of Group III-V are drawn to *in vivo* identifying compounds that ameliorate symptoms associated with a disease, to treating a disease, or to causing a desired biological effect.

The inventions of Groups III-V are patentably distinct because they are drawn to methods that have distinct steps and require different compositions for practice. For example, the method of Group III is drawn to *in vivo* identifying compounds that ameliorate symptoms associated with a disease (i.e., screening), which is not the same as treating a disease, or to causing a desired biological effect. Similarly, treating a disease is not the same as causing a desired biological effect, since causing a desired biological effect does not necessarily lead to treatment.

The species election is proper because they are drawn to distinct compositions that require distinct searches in the paten and non-patent literature.

Examination of anything more than one of the above designated inventions and species would pose a serious burden to the examiner.

9. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ileana Popa

Janet L. Epps-Ford
Primary Examiner
AU 1633